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Michael Bazylenko
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EXAMINER

BHAT, NARAYAN KAMESHWAR

ART UNIT

PAPER NUMBER

1634

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,482

Applicant(s)

BAZYLENKO, MICHAEL

Examiner

NARAYAN K. BHAT

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-8 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed January 27, 2009. Applicant's arguments filed January 27, 2009 have been fully considered but they are not persuasive for the reasons listed in this office action. Accordingly, **THIS ACTION IS MADE FINAL.**

Status of the Claims

2. This action is in response to papers filed on January 27, 2009.
3. Claims 1, 4-8 and 10-20 are pending in this application.
4. Claims 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Applicant's election of the restriction requirement without traverse in the reply filed on February 13, 2008 made final in the office action mailed April 16, 2008.
5. Claims 1, 4-8 and 10-15 are under examination.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Previous rejections are maintained in view of Applicant not amending the following claims.

7. Claims 7, 8 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 7 recites the limitation of "the thin film light source" in line 1. There is insufficient antecedent basis for this limitation in the claim 4. It is suggested that the claim be amended properly to depend from the "light source" or "thin film semiconductor" of claim 4.

9. Claim 8 recites the limitation of "the thin film photodetector" in line 1. There is insufficient antecedent basis for this limitation in the claim 4. It is suggested that the claim be amended properly to depend from the "photodetector" or "thin film semiconductor" of claim 4.

10. Claim 14 recites the limitation "comprises a further plurality of electrodes" in line 2. There is insufficient antecedent basis for this limitation because claim 1 does not recite an electrode. It is suggested that the claim be amended, e.g. "biochip further comprises a plurality of electrodes" to provide proper antecedent basis.

11. Claim 15 is indefinite because it is dependent from claim 14.

Claim Interpretation

35 U.S.C. 112, sixth paragraph

12. Claims 1 and 10-13 are written using means-plus- function language. The MPEP § 2181-2184 provides guidance for claim evaluation and examination under 35 U.S.C. 112, Sixth Paragraph as set forth below:

The USPTO must apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application. See *Donaldson*, 16 F.3d at

1194, and 29 USPQ2d at 1850 (stating that 35 U.S.C. 112, sixth paragraph "merely sets a limit on how broadly the PTO may construe means-plus-function language under the rubric of reasonable interpretation". The Federal Circuit has held that applicants (and reexamination patentees) before the USPTO have the opportunity and the obligation to define their inventions precisely during proceedings before the PTO. See *In re Morris*, 127 F.3d 1048, 1056-57, 44 USPQ2d 1023, 1029-30 (Fed. Cir. 1997).

A claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function. (see MPEP § 2181(I)).

13. The limitation of "means for determining a specific binding event at each binding site" in claim 1 (lines 2 and 6-7), is not being treated under 35 USC 112, sixth paragraph because the claim does not meet the third prong of the 3-prong analysis because "means" is defined by structure, i.e., light source and photodetector and planar waveguide. Therefore, means will be given broadest reasonable interpretation.

14. The limitation "means for determining a refractive index change" in claim 10, line 2 is being treated under 35 USC 112, sixth paragraph as it meets the 3-prong analysis. Therefore, "means" is interpreted to encompass the means as described in the specification (e.g., pg. 17, lines 28-34) or functional equivalents of first and second planar waveguide.

15. The limitation of "means for determining a refractive index change" in claims 11 and 12, is not being treated under 35 USC 112, sixth paragraph because the claim does not meet the third prong of the 3-prong analysis because "means" is defined by

structure, i.e., first and second planar waveguide. Therefore, means will be given broadest reasonable interpretation.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obremski et al (USPN 6,110,749 issued Aug. 29, 2000) in view of Duveneck et al (USPN 6,395,558 issued May 28, 2002).

Claim 1 recites following structural features: a) a plurality of binding sites with monolithically integrated with optical means, b) a light source, c) a photodetector and d) a planar waveguide. Obremski et al teaches all the structural features except for the integration of optical means with the binding sites, which is taught by Duveneck et al as described below.

Regarding structural components 'a' and 'd', Obremski et al teaches a biochip for testing biological substances comprising a plurality of binding sites (Fig. 1, # 22, column 4, line 1) on a planar waveguide (Fig. 1, # 24, column 4, line 2).

Obremski et al also teaches a light source (Fig. 5, # 38, column 12, line 11, structural component 'b') and a photodetector (Fig. 5, # 64, column 14, line 14, structural component 'c'), which are optical means for determining a specific binding

event at each binding sites. Obremski et al also teaches an evanescent field of light propagating in the waveguide interacting with the biological substance under test (Fig. 5, # 30, column 10, lines 19-27). Obremski et al are silent about monolithic integration of light source and photodetector at the binding site.

Regarding claim 10, Obremski et al teaches a planar waveguide (Fig. 2, # 24) and another layer (Fig. 2, # 32) with modified refractive index (Fig. 2, # 32, column 9, lines 63-67 and column 10, lines 13-14) and further teaches evanescent means for determining a binding event at each specific site (abstract). Obremski et al are silent about first and second planar waveguides as means for determining a refractive index change associated with a binding event.

Regarding claims 11 and 12, Obremski et al are silent about first and second planar waveguide separated by coupling layer and the second planar waveguide comprising grating.

Regarding claim 13, Obremski et al teaches a light path on the probe with the target and without target (column 2, lines 29-35) and the light path without the target is the reference light path as defined in the instant specification (instant specification, pg. 20, line 1). It is noted that "for error correction" is a recitation of the intended use.

Regarding claim 1, Obremski et al are silent about monolithic integration of light source and detector with binding sites.

Regarding claims 11 and 12, Obremski et al are silent about first and second planar waveguide separated by coupling layer and the second planar waveguide comprising grating.

However, monolithic integration of light source and detector with binding sites and separation of first and second planar waveguides by a coupling layer, wherein the second planar waveguide comprises grating were known in the art at the time of the claimed invention was made as taught by Duveneck et al.

Duveneck et al teaches a biochip for testing biological substance comprising a planar sensor containing transducer and recognition layer (Fig. 1, # c) and further teaches transducer consists of a substrate (Fig. 1, # a), an intermediate layer, a waveguide layer (Fig. 1, # b) and an adhesion promoting layer (column 2, lines 14-23 and lines 56-57). Duveneck et al also teaches both the light source and the detector are integrated into the sensor platform, i.e., binding sites (column 3, lines 66-67). Instant specification defines monolithically integrated chip as a chip produced by processing only one substrate in a series of deposition and etching steps (paragraph 0011). Duveneck et al teaches the monolithic integrated optical immuno sensors (column 15, lines 56-57) and photolithographic and etching process (column 8, lines 9-10). Therefore combined teachings of Duveneck et al are reasonably interpreted as plurality of binding sites monolithically integrated with the optical means.

Duveneck et al explicitly teaches that the first planar waveguide and second planar waveguide separated by coupling layer (column 7, lines 11-16) and a means for determining the refractive index changes associated with a binding event (column 2, lines 60-65, limitations of instant claims 10 and 11).

Duveneck et al also teaches that the grating is formed on the first wave guide (column 3, lines 5-8) and further teaches a second planar wave guide located below the

first wave guide and separated by coupling layer of lower refractive index than that of the two waveguides (column 7, lines 11-16), thus teaching a means for determining the refractive index changes associated with a binding event as claimed (column 2, lines 60-65, limitations of instant claim 12).

Duveneck et al also teaches monolithic integration of optical means with the binding site provides higher signal stability without any background interfering signals (column 4, lines 2-12).

Monolithic integration of optical source at each binding sites in the device of Obremski et al increases the signal stability without interference of the background signal as taught by Duveneck et al, thus increasing the sensitivity of target detection.

It would have been prima facie obvious to one having the ordinary skill in the art at the time of the claimed invention was made to modify the optical means of detection of Obremski et al with the monolithic integration of optical means at the binding site of Duveneck et al with a reasonable expectation of success with the expected benefit of providing higher signal stability without any background interfering signals as taught by Duveneck et al (column 4, lines 2-12).

18. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obremski et al (USPN 6,110,749 issued Aug. 29, 2000) in view of Duveneck et al (USPN 6,395,558 issued May 28, 2002) as applied to claim 1 as above and further in view of Sickmiller (USPN 6,214,733 issued Apr. 10, 2001).

Teachings of Obremski et al and Duveneck et al regarding claim 1 are described above in section 17.

Regarding claims 4 and 5, Duveneck et al teaches that light source and detector are integrated into the sensor platform (column 3, lines 66-67).

Regarding claim 6, Obremski et al and Duveneck et al are silent about semiconductor thin film comprises semiconductor polymer.

Obremski et al and Duveneck et al are silent about substrate comprising a thin film semiconductor. However, thin film semiconductor was known in the art at the time of the claimed invention was made as taught by Sickmiller.

Sickmiller teaches a device comprising thin film semiconductor (Fig. 1, device # 10, thin film semiconductor # 12, column 2, and line 54) and further teaches that light source and transistors, i.e., photodetector are implemented in thin film conductor (column 2, lines 65-67). Sickmiller also teaches semiconductor thin film material comprises polymer (column 2, line 9). Sickmiller also teaches that thin film semiconductor is mechanically flexible and increases optical efficiency of optoelectronic devices and increases electrical performances of semiconductor devices (column 9, lines 49-56).

It would have been prima facie obvious to one having the ordinary skill in the art at the time of the claimed invention was made to modify the optical means of Obremski et al with the thin film semiconductor optical means of Sickmiller with a reasonable expectation of success with the expected benefit of having a thin film semiconductor

with mechanical flexibility, increasing optical efficiency and electrical performances as taught by Sickmiller (column 9, lines 49-56).

19. Claims 1, 4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obremski et al (USPN 6,110,749 issued Aug. 29, 2000), Duveneck et al (USPN 6,395,558 issued May 28, 2002) Sickmiller (USPN 6,214,733 issued Apr. 10, 2001) as applied to claims 1 and 4 as above and further in view of Little et al (USPGPUB NO. 2004/0101861 filed Nov. 17, 2002).

Teachings of Obremski et al, Duveneck et al and Sickmiller regarding claims 1 and 4 are described in section 18 and 19 of this office action.

Regarding claims 7 and 8, Duveneck et al teaches the light source and photodetector (column 3, lines 66-67). Obremski et al, Duveneck et al and Sickmiller are silent about thin film light source and thin film photodetector are microcavity light source and photodetector. However, microcavity light source and microcavity photodetector were known in the art at the time of the claimed invention was made as taught by Little et al.

Little et al teaches that the thin film light source is a resonant cavity, i.e., a microcavity light source (Fig. 5A, # 58, paragraphs 0050-0053) and further teaches that the thin film photodetector is a resonant cavity, i.e., a microcavity photodetector (Fig. 5A, # 60, paragraphs 0050-0053). Little et al also teaches that microcavity light source and photodetectors provides a means for efficient optical detection at the microlocations on the substrate and enhances the detection sensitivity (paragraphs 0013 and 0035).

It would have been prima facie obvious to one having the ordinary skill in the art at the time of the claimed invention was made to modify the light source and photodetector of Obremski et al, Duveneck et al and Sickmiller with the thin film microcavity light source and photodetector of Little et al with a reasonable expectation of success with the expected benefit of having microcavity light source and photodetectors providing a means for efficient optical detection at the microlocations on the substrate and enhancing the detection sensitivity as taught by Little et al (paragraphs 0013 and 0035).

20. Claims 1 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obremski et al (USPN 6,110,749 issued Aug. 29, 2000) in view of Duveneck et al (USPN 6,395,558 issued May 28, 2002) as applied to claims 1 as above and further in view of McFarland et al (USPGPUB NO. 2003/0104481 published Jun. 5, 2003).

Regarding claims 14 and 15, Obremski et al teaches a planar waveguide device comprising a plurality of location on the surface comprising nucleic acid probe and further teaches detection of target by hybridization to the probe (column 4, lines 4-10 and column 7, lines 39-47). Obremski et al and Duveneck et al are silent about a plurality of electrodes at each binding site to control the hybridization.

However, a plurality of electrodes at a binding site was known in the art at the time of the claimed invention was made as taught by McFarland et al, who teaches an apparatus comprising a substrate comprising a plurality of electrodes (paragraph 0044) for controlling hybridization condition at each binding site (paragraph 0064). McFarland

et al also teaches electrodes comprise resistive heater electrode formed underneath binding sites (Fig. 5, # 505, paragraphs 0054 and 0071-0072). McFarland et al also teaches that the electrodes provides a means for generating addressable arrays of compounds varying in composition concentration, stoichiometry and thickness and for controlling reaction and hybridization (paragraphs 0010 and 0011).

It would have been prima facie obvious to one having the ordinary skill in the art at the time of the claimed invention was made to modify the substrate of Obremski et al and Duveneck et al with the substrate comprising electrode of McFarland et al with a reasonable expectation of success with the expected benefit of having heat resistive electrodes for generating addressable arrays of compounds varying in composition concentration, stoichiometry and thickness and for controlling reaction and hybridization as taught by McFarland et al (paragraphs 0010 and 0011).

Response to remarks from the Applicants

Claim Rejections under 35 U.S.C. § 112 Second Paragraph

21. Applicant has not amended the claims 7, 8 and 14 and therefore rejections under 35 USC 112 Second Paragraph are maintained (Remarks, pg. 2, paragraph 5).

Claim Rejections under 35 U.S.C. § 103(a)

22. Applicant's arguments filed January 27, 2009 with respect to claims 1 and 10-13 have been fully considered but are not persuasive for the following reasons.

Applicant points out that monolithic integration have the cost and performance advantage (Remarks, pg. 1, paragraph 1). Applicant's remarks are noted.

The instant specification defines monolithically integrated chip as a chip produced by processing only one substrate in a series of deposition and etching steps (paragraph 0014). Duveneck et al teaches the monolithic integrated optical immuno sensors (column 15, lines 56-57) and photolithographic and etching process (column 8, lines 9-10). Duveneck et al also teaches sensor is produced by processing single substrate (Fig. 1 and column 2, lines 14-23) and further teaches that light source and detectors are integrated into the substrate at the binding site (column 3, lines 66-67), i.e., sensor is produced by processing a single substrate, which is reasonably interpreted as plurality of binding sites monolithically integrated with the optical means.

Applicant further argues that there is no mentioning of word monolithic integration in Duveneck et al (Remarks, pg. 1, paragraph 1). This argument is not persuasive because Duveneck et al teaches the unified structure produced by processing only one substrate (Fig. 1, column 15, lines 56-57). Therefore Applicant's arguments are not persuasive.

Applicant further reiterates that Duveneck et al teaches away from the monolithic integration (Remarks, pg. 1, paragraph 3). This argument is not persuasive because Duveneck et al teaches a chip produced from a single substrate (Fig. 1), which is monolithic integration as defined in the instant specification (paragraph 0014).

With regard to Applicant's argument that the "whole structure is contained within a single monolithically integrated chip", it is noted that the combined teachings

Duveneck et al and Obremski et al teach all required element of in a single chip as recited in claim 1. Therefore arguments are not persuasive.

Applicant points out that he can not identify the intermediate layer of Duveneck et al in the cited reference (Remarks, pg. 2, paragraph 1). Duveneck et al teaches an intermediate layer (column 2, line 17).

Applicant's argues that there is a difference between resonant cavity light of Little et al and microcavity light of the instant claims (Remarks, pg. 2, paragraph 3). This argument is not persuasive because Applicant has not pointed out structural difference between the resonant cavity lights and microcavity lights.

Applicant argues that the electrodes of McFarland et al are not employed for controlling hybridization (Remarks, pg. 2, paragraph 4). This argument is not persuasive because claims are rejected based on the structural components of the biochip rather than their intended use (MPEP 2114).

Note to the Applicant

23. Applicant is encouraged to contact the Examiner to discuss further how claim can be amended to over come the prior art and possibly to identify allowable subject matter.

Conclusion

24. No claims are allowed.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634